



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to silicon and protection against aluminium accumulation in the brain (ID 290), “cardiovascular health” (ID 289), forming a protective coat on the mucous membrane of the stomach (ID 345), neutralisation of gastric acid (ID 345), contribution to normal formation of collagen and connective tissue (ID 287, 288, 333, 334, 335, 1405, 1652, 1718, 1719, 1945), maintenance of normal bone (ID 287, 335, 1652, 1718, 1945), maintenance of normal joints (ID 1405, 1652, 1945), maintenance of normal appearance and elasticity of the skin (ID 288, 333), and contribution to normal formation of hair and nails (ID 334, 1652, 1719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to silicon and protection against aluminium accumulation in the brain (ID 290), “cardiovascular health” (ID 289), forming a protective coat on the mucous membrane of the stomach (ID 345), neutralisation of gastric acid (ID 345), contribution to normal formation of collagen and connective tissue (ID 287, 288, 333, 334, 335, 1405, 1652, 1718, 1719, 1945), maintenance of normal bone (ID 287, 335, 1652, 1718, 1945), maintenance of normal joints (ID 1405, 1652, 1945), maintenance of normal appearance and elasticity of the skin (ID 288, 333), and contribution to normal formation of hair and nails (ID 334, 1652, 1719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to silicon and protection against aluminium accumulation in the brain, cardiovascular health, forming a protective coat on the mucous membrane of the stomach, neutralisation of gastric acid, contribution to normal formation of collagen and connective tissue, maintenance of normal

¹ On request from the European Commission, Question No EFSA-Q-2008-1074, EFSA-Q-2008-1075, EFSA-Q-2008-1076, EFSA-Q-2008-1077, EFSA-Q-2008-1120, EFSA-Q-2008-1121, EFSA-Q-2008-1122, EFSA-Q-2008-1132, EFSA-Q-2008-2142, EFSA-Q-2008-2388, EFSA-Q-2008-2454, EFSA-Q-2008-2455, EFSA-Q-2008-2678, adopted on 25 March 2011.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Bone/Teeth/Connective Tissue: Rikke Andersen, Olivier Bruyère, Albert Flynn, Ingegerd Johansson, Jukka Meurman and Hildegard Przyrembel. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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bone, maintenance of normal joints, maintenance of normal appearance and elasticity of the skin, and contribution to normal formation of hair and nails. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is silicon. The Panel considers that silicon is sufficiently characterised.

Protection against aluminium accumulation in the brain

The claimed effect is “mental health”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to protection against aluminium accumulation in the brain. The Panel considers that protection against aluminium accumulation in the brain might be a beneficial physiological effect.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and protection against aluminium accumulation in the brain.

“Cardiovascular health”

The claimed effect is “cardiovascular health”. The target population is assumed to be the general population. The claimed effect is not sufficiently defined and no further details were provided in the proposed wording. No further clarifications were provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Forming a protective coat on the mucous membrane of the stomach

The claimed effect is “gut health”. The target population is assumed to be the general population. From the clarifications provided by Member States, the Panel assumes that the claimed effect refers to forming a protective coat on the mucous membrane of the stomach. The Panel considers that forming a protective coat on the mucous membrane of the stomach is not a beneficial physiological effect *per se*, but needs to be linked to a beneficial physiological or clinical outcome. The Panel considers that no evidence has been provided to indicate in which context the claimed effect could be considered to be a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and a beneficial physiological effect related to forming a protective coat on the mucous membrane of the stomach.

Neutralisation of gastric acid

The claimed effect is “gut health”. The target population is assumed to be the general population. From the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the neutralisation of gastric acid. The Panel considers that the evidence provided does not establish that the neutralisation of gastric acid is a beneficial physiological effect for the general population.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and a beneficial physiological effect for the general population related to the neutralisation of gastric acid.

Contribution to normal formation of collagen and connective tissue

The claimed effects are “silicon is required for normal bone and connective tissue formation”, “normal skin, hair and nails”, “maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis”, “helps support hair quality by helping to maintain healthy connective tissue in the dermis”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis”, “stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks, protection against”, “essential part of the connective tissues, skin and hair”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis, healthy women and men”, “helps support hair quality by helping to maintain healthy connective tissue in the dermis, healthy women and men”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effects refer to contribution to normal formation of collagen and connective tissue. The Panel considers that contribution to normal formation of collagen and connective tissue is a beneficial physiological effect.

No human studies which addressed the effects of silicon intake on collagen or connective tissue formation have been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and contribution to normal formation of collagen or connective tissue.

Maintenance of normal bone

The claimed effects are “silicon is required for normal bone and connective tissue formation”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis”, “essential part of the connective tissues, skin and hair”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis, healthy women and men”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal bone. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that a randomised, double-blind, placebo-controlled, human intervention study did not show an effect of silicon administration (as ch-OSA) on bone mineral density at any site in post-menopausal women, that the findings of a cross-sectional study on the association between silicon intakes and bone mineral density were inconsistent, and that no evidence for a mechanism by which silicon could exert the claimed effect has been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and maintenance of normal bone.

Maintenance of normal joints

The claimed effects are “stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks, protection against”, “essential part of the connective tissues, skin and hair”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed

effects refer to the maintenance of normal joints. The Panel considers that maintenance of normal joints is a beneficial physiological effect.

No human studies which addressed the effects of silicon withdrawal or silicon intake on joint function have been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and maintenance of normal joints.

Maintenance of normal appearance and elasticity of the skin

The claimed effects are “normal skin, hair and nails” and “maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis”. The target population is assumed to be the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal appearance and elasticity of the skin. The Panel notes that the evidence provided does not establish that changes in the appearance or elasticity of the skin relate to changes in skin function.

The Panel considers that the claim does not refer to a function of the body as required by Regulation (EC) No 1924/2006.

Contribution to normal formation of hair and nails

The claimed effects are “helps support hair quality by helping to maintain healthy connective tissue in the dermis”, “essential part of the connective tissues, skin and hair”, and “helps support hair quality by helping to maintain healthy connective tissue in the dermis, healthy women and men”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the contribution to normal formation of hair and nails. The Panel considers that contribution to normal formation of hair and nails is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and contribution to normal formation of hair and nails.

KEY WORDS

Silicon, aluminium, cardiovascular, stomach, collagen, connective tissue, bone, joints, skin, hair, nails, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituents that are the subjects of the health claims are “silicon”, “silicon (as stabilised oligomeric orthosilicic acid (OSA))”, “choline-stabilised orthosilicic acid (ch-OSA)”, “Mineralwasser/Kieselsäure (Silizium)”, “silica/silicious earth”, and “monométhylsilanetriol”.

From the references and conditions of use provided in relation to the health claims considered in this opinion, the Panel assumes that the food constituent under evaluation is silicon.

Silicon is authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006⁶ and Annex I of Directive 2002/46/EC⁷). This evaluation applies to silicon naturally present in foods and added to foods.

Silicon occurs naturally in foods as silicon dioxide (silica, SiO₂) and silicates, and may also be added to foods as an anti-caking and anti-foaming agent in the form of silica, silicates and dimethylpolysiloxane. Silicate-containing antacids have been widely used for a number of decades.

Orthosilicic acid [Si(OH)₄] or mono-silicic acid is a water soluble form of silicon. A saturated solution contains 0.1 % silicic acid. Silicic acid can also exist as an oligomer and as polysilicic acid (EFSA, 2004). Oligomeric silica (oligomeric orthosilicic acid) is formed as a meta-stable intermediate in the progressive polymerisation of silicic acid in saturated solutions. Monomethylsilanetriol, also called organic silicon (CH₃-Si-(OH)₃), and choline-stabilised orthosilicic acid (ch-OSA) are usually added to food supplements as a source of silicon (EFSA, 2009a, 2009b).

The Panel considers that the food constituent, silicon, which is the subject of the health claims, is sufficiently characterised.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

⁶ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

2. Relevance of the claimed effect to human health

2.1. Protection against aluminium accumulation in the brain (ID 290)

The claimed effect is “mental health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to protection against aluminium accumulation in the brain.

The Panel considers that protection against aluminium accumulation in the brain might be a beneficial physiological effect.

2.2. “Cardiovascular health” (ID 289)

The claimed effect is “cardiovascular health”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. No further clarifications were provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.3. Forming a protective coat on the mucous membrane of the stomach (ID 345)

The claimed effect is “gut health”. The Panel assumes that the target population is the general population.

From the clarifications provided by Member States, the Panel assumes that the claimed effect refers to forming a protective coat on the mucous membrane of the stomach.

The Panel considers that forming a protective coat on the mucous membrane of the stomach is not a beneficial physiological effect *per se*, but needs to be linked to a beneficial physiological or clinical outcome. The Panel notes that no evidence has been provided to indicate the context in which the claimed effect could be considered to be a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and a beneficial physiological effect related to forming a protective coat on the mucous membrane of the stomach.

2.4. Neutralisation of gastric acid (ID 345)

The claimed effect is “gut health”. The Panel assumes that the target population is the general population.

From the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the neutralisation of gastric acid.

The Panel considers that the evidence provided does not establish that the neutralisation of gastric acid is a beneficial physiological effect for the general population.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and a beneficial physiological effect for the general population related to the neutralisation of gastric acid.

2.5. Contribution to normal formation of collagen and connective tissue (ID 287, 288, 333, 334, 335, 1405, 1652, 1718, 1719, 1945)

The claimed effects are “silicon is required for normal bone and connective tissue formation”, “normal skin, hair and nails”, “maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis”, “helps support hair quality by helping to maintain healthy connective tissue in the dermis”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis”, “stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks, protection against”, “essential part of the connective tissues, skin and hair”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis, healthy women and men”, “helps support hair quality by helping to maintain healthy connective tissue in the dermis, healthy women and men”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The Panel assumes that the target population is the general population.

Collagen is a structural component of several tissues in the body including bone, cartilage, gums, skin, tendons and blood vessels.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effects refer to the contribution to normal formation of collagen and connective tissue.

The Panel considers that contribution to normal formation of collagen and connective tissue is a beneficial physiological effect.

2.6. Maintenance of normal bone (ID 287, 335, 1652, 1718, 1945)

The claimed effects are “silicon is required for normal bone and connective tissue formation”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis”, “essential part of the connective tissues, skin and hair”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis, healthy women and men”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal bone.

The Panel considers that maintenance of normal bone is a beneficial physiological effect.

2.7. Maintenance of normal joints (ID 1405, 1652, 1945)

The claimed effects are “stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks, protection against”, “essential part of the connective tissues, skin and hair”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal joints.

The Panel considers that maintenance of normal joints is a beneficial physiological effect.

2.8. Maintenance of normal appearance and elasticity of the skin (ID 288, 333)

The claimed effects are “normal skin, hair and nails”, and “maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of the normal appearance and elasticity of the skin. The Panel notes that the evidence provided does not establish that changes in the appearance or elasticity of the skin relate to changes in skin function.

The Panel considers that the claim does not refer to a function of the body as required by Regulation (EC) No 1924/2006.

2.9. Contribution to normal formation of hair and nails (ID 334, 1652, 1719)

The claimed effects are “helps support hair quality by helping to maintain healthy connective tissue in the dermis”, “essential part of the connective tissues, skin and hair”, and “helps support hair quality by helping to maintain healthy connective tissue in the dermis, healthy women and men”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the contribution to normal formation of hair and nails.

The Panel considers that contribution to normal formation of hair and nails is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Silicon is considered an ultra-trace element for which a functional role in humans has not been identified. As the essentiality of silicon for humans has not been established, a dietary reference value for silicon has not been set (IoM, 2000).

A number of narrative reviews on the health effects of silicon containing no original data for a scientific evaluation, post-mortem studies in humans assessing the content of silicon in various tissues (e.g. blood vessels), and human intervention studies on silicon supplementation for the treatment of acne were provided. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

The vast majority of the references provided for the scientific substantiation of the claims reported on animal studies which addressed the effects of silicon-free diets and/or the effects of reintroducing silicon into the diet on the structure and morphology of various tissues and/or organs, including collagen and bone. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of silicon withdrawal or silicon intake in humans.

3.1. Protection against aluminium accumulation in the brain (ID 290)

In one intervention study, patients with Alzheimer's disease were asked to drink 1.5 L of a silicic acid-rich mineral water each day for five days (Exley et al., 2006). Patients' urinary excretion of

aluminium was determined pre- and post-intervention. The Panel notes that no measures of aluminium retention in the body or accumulation in the brain were undertaken. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

One epidemiological study examined the association between silicon dioxide (silica) and aluminium concentrations in drinking water and the risk of cognitive impairment using data from a population-based survey in 3,777 French subjects aged 65 years and older (Jacqmin-Gadda et al., 1996). In an eight-year follow up of the same cohort, the relationship between aluminium and silica concentrations in drinking water and the risk of dementia and Alzheimer's disease was investigated (Rondeau et al., 2000). A further epidemiological study explored the association between the composition of drinking water and cognitive function and the risk of Alzheimer's disease in women taking part in the Epidemiology of Osteoporosis (EPIDOS) study (n=7,598) (Gillette-Guyonnet et al., 2005). The Panel notes that no endpoint directly related to aluminium accumulation in the brain was measured in these epidemiological studies. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One animal study examined the effect of silicon supplementation on tissue aluminium retention in rats, and one *in vitro* study examined the chemistry of aluminium binding by silicic acid. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of silicon consumption on protection against aluminium accumulation in the brain *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and protection against aluminium accumulation in the brain.

3.2. Contribution to normal formation of collagen and connective tissue (ID 287, 288, 333, 334, 335, 1405, 1652, 1718, 1719, 1945)

No evidence has been provided that silicon plays a role in collagen formation in humans, and no human studies which addressed the effects of silicon intake on collagen or connective tissue formation have been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and contribution to normal formation of collagen and connective tissue.

3.3. Maintenance of normal bone (ID 287, 335, 1652, 1718, 1945)

One human retrospective study on intramuscular administration of silicon on bone mineral density (BMD) was provided (Eisinger and Clairret, 1993). The Panel notes that the intra-muscular route is not relevant to human nutrition. One abstract reporting on a human intervention study on the effects of oral consumption of silicon on bone turnover and BMD, and one abstract reporting on a human observational study on the association between dietary silicon consumption and BMD, which included insufficient data for a full scientific evaluation were also provided (Jugdaohsingh et al., 2003; Spector et al., 2005). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One human intervention study on the effects of silicon consumed orally at doses of 5.5 g/day for 20 days per month for three months (n=14) vs. no intervention (n=15) on trabecular bone volume measured by bone biopsy was provided (Schiano et al., 1979). The Panel notes that the study was not placebo-controlled, that it is unclear whether the subjects were randomly assigned to the intervention and control groups, and that no information was provided about blinding or the statistical analyses performed. The Panel notes the poor methodological reporting and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

One randomised, double-blind, placebo-controlled human intervention study investigated the effects of silicon as choline-stabilised orthosilicic acid (ch-OSA) in association with calcium (1,000 mg/day) and cholecalciferol (20 µg/day), administered for 12 months, on BMD and markers of bone turnover in 184 osteopenic post-menopausal women (Spector et al., 2008). Women were randomly assigned to consume ch-OSA at doses of 3, 6 and 12 mg silicon/day (3, 6 and 12 drops) or placebo (3, 6 or 12 drops to mimic the intervention) plus calcium and cholecalciferol. BMD was measured by dual-energy x-ray absorptiometry (DXA) at the beginning and end of the study, whereas markers of bone formation (osteocalcin (OC), bone specific alkaline phosphatase (BAP) and procollagen type I N-terminal propeptide (PINP)) and of bone resorption (deoxypyridoline (DPD) and C-terminal telopeptide of type I collagen (CTX-I)) were assessed at baseline and at 6 and 12 months of the study. It was estimated that 175 subjects needed to be recruited to observe a 25 % difference between ch-OSA and placebo groups on markers of bone turnover with an $\alpha < 0.05$ and a power of 85 %, taking into account a drop-out rate of 20 %. Statistical analysis and baseline characteristics of subjects were provided for the population of completers only (n=136, n=37 in the placebo group and n=33 in each ch-OSA group). *Post-hoc* sub-group analyses were carried out for changes in femoral BMD in women with a femoral BMD T-score < -1 . The Panel notes that these *post-hoc* comparisons were not pre-planned, and that no adjustments for multiple testing were performed. Intervention and placebo groups were not comparable at baseline for markers of bone turnover or BMD. No significant differences in BMD changes between the intervention and placebo groups were observed during the 12-month intervention. Changes in markers of bone turnover were not significantly different between groups (OC, BAP, DPD), except for PINP, which at 12 months was significantly lower in the 6 and 12 mg ch-OSA groups than in the placebo group. The Panel notes that this study does not show an effect of ch-OSA on BMD in post-menopausal women.

One cross-sectional, population-based study including 2,847 subjects (306 pre-menopausal women, 1,325 post-menopausal women, 1,295 men) from the Framingham Offspring Cohort assessed the association between dietary silicon intake and BMD at the hip and lumbar spine (Jugdaohsingh et al., 2004). Dietary intake of silicon was assessed using a food frequency questionnaire and BMD was investigated by DXA. After adjustment for confounders known to affect BMD (age, height, body mass index, physical activity, calcium and vitamin D intakes, and certain medications), silicon intakes correlated positively with BMD at four hip sites in men and pre-menopausal women, but not in post-menopausal women, whereas no significant association was found between silicon intake and BMD in the lumbar spine for any group. The Panel notes that the findings of this cross-sectional study on the association between silicon intakes and BMD were inconsistent, and that no suitable explanation for a differential effect of silicon in different population sub-groups and in different bone sites has been provided.

The Panel notes that no human intervention studies addressing the effects of silicon intakes on BMD in men or pre-menopausal women have been submitted, and that no evidence for a mechanism by which silicon could exert an effect on bone has been provided.

In weighing the evidence, the Panel took into account that a randomised, double-blind, placebo-controlled human intervention study did not show an effect of silicon administration (as ch-OSA) on BMD at any site in post-menopausal women, that the findings of a cross-sectional study on the association between silicon intakes and BMD were inconsistent, and that no evidence for a mechanism by which silicon could exert the claimed effect has been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and maintenance of normal bone.

3.4. Maintenance of normal joints (ID 1405, 1652, 1945)

No evidence has been provided that silicon plays a role in the maintenance of normal joints in humans, and no human studies which addressed the effects of silicon intake on joint function have been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and maintenance of normal joints.

3.5. Contribution to normal formation of hair and nails (ID 334, 1652, 1719)

In an open label, uncontrolled intervention study (Lassus, 1993), the effects of colloidal silicic acid, taken orally (10 mL once daily) and applied topically to the face for 10 min during 90 days, on “thickness and turgor of the skin, wrinkles and condition of the hair and nails” in 50 women with “biologically aged” skin and fragile or thin hair, or brittle nails, were investigated. The Panel notes the uncontrolled nature of the study and considers that no conclusions can be drawn from it for the scientific substantiation of the claim.

One randomised, double-blind, placebo-controlled intervention study (Wickett et al., 2007) investigated the effects of silicon as ch-OSA (10 mg/day, n=24) taken orally for nine months vs. placebo (microcrystalline cellulose, n=24) on hair morphology and hair tensile properties in women (18-65 years) with fine hair as assessed at baseline by a professional hairdresser on a visual analogue scale (3-point scale: fine, normal and thick). Outcome measures for hair tensile properties (n=5), both within groups and between groups, were assessed using Wilcoxon tests for paired comparisons and Mann-Whitney U tests for independent samples, respectively, in completers only (22 and 23 in the intervention and placebo groups, respectively). In addition, several morphology parameters were determined but only changes in the cross-sectional area of the hair, in the minor axis and in the major axis are reported. The Panel notes that no power calculations were performed, that the primary outcome measure was not identified, that a high number of outcome variables were tested, and that adjustments for multiple comparisons were not performed. The Panel considers that because of the important methodological limitations identified no conclusions can be drawn from this study for the scientific substantiation of the claim.

One randomised, double blind, placebo controlled human intervention study (Barel et al., 2005) investigated the effects of silicon as ch-OSA (10 mg/day, n=25) taken orally for 20 weeks vs. placebo (microcrystalline cellulose, n=25) on skin, hair and nail parameters in women (40-65 years) with “clear signs of photo-aging of facial skin” (not better defined). A total of five outcome measures were related to the skin, whereas the outcome measure for hair and nails was the degree of brittleness on a 4-point scale (no brittle hair/nails; slight, moderate and severe brittleness). Changes in all of the parameters were assessed both within groups and between groups using Wilcoxon tests for paired comparisons and Mann-Whitney U tests for independent samples, respectively. The Panel notes that no power calculations were performed, that the primary outcome was not identified, that a high number of outcome variables were tested, and that adjustment for multiple comparisons was not performed. The Panel also notes that it is not stated who or how many “assessors” evaluated the study subjects for brittleness of hair and nails, or which criteria were used for the evaluation. The Panel considers that because of the important methodological limitations identified no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of silicon and contribution to the normal formation of hair and nails.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, silicon, which is the subject of the health claims, is sufficiently characterised.

Protection against aluminium accumulation in the brain (ID 290)

- The claimed effect is “mental health”. The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effect refers to protection against aluminium accumulation in the brain. Protection against aluminium accumulation in the brain might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of silicon and protection against aluminium accumulation in the brain.

“Cardiovascular health” (ID 289)

- The claimed effect is “cardiovascular health”. The target population is assumed to be the general population. The claimed effect has not been sufficiently defined.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Forming a protective coat on the mucous membrane of the stomach (ID 345)

- The claimed effect is “gut health”. The target population is assumed to be the general population. From the clarifications provided by Member States, it is assumed that the claimed effect refers to forming a protective coat on the mucous membrane of the stomach. No evidence has been provided to indicate the context in which the claimed effect could be considered to be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of silicon and a beneficial physiological effect related to forming a protective coat on the mucous membrane of the stomach.

Neutralisation of gastric acid (ID 345)

- The claimed effect is “gut health”. The target population is assumed to be the general population. From the clarifications provided by Member States, it is assumed that the claimed effect refers to the neutralisation of gastric acid. The evidence provided does not establish that the neutralisation of gastric acid is a beneficial physiological effect for the general population.
- A cause and effect relationship has not been established between the consumption of silicon and a beneficial physiological effect for the general population related to the neutralisation of gastric acid.

Contribution to normal formation of collagen and connective tissue (ID 287, 288, 333, 334, 335, 1405, 1652, 1718, 1719, 1945)

- The claimed effects are “silicon is required for normal bone and connective tissue formation”, “normal skin, hair and nails”, “maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis”, “helps support hair quality by helping to maintain healthy connective tissue in the dermis”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis”, “stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks, protection

against”, “essential part of the connective tissues, skin and hair”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis, healthy women and men”, “helps support hair quality by helping to maintain healthy connective tissue in the dermis, healthy women and men”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, it is assumed that the claimed effects refer to contribution to normal formation of collagen and connective tissue. Contribution to normal formation of collagen and connective tissue is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of silicon and contribution to normal formation of collagen and connective tissue.

Maintenance of normal bone (ID 287, 335, 1652, 1718, 1945)

The claimed effects are “silicon is required for normal bone and connective tissue formation”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis”, “essential part of the connective tissues, skin and hair”, “maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis, healthy women and men”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the maintenance of normal bone. Maintenance of normal bone is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of silicon and maintenance of normal bone.

Maintenance of normal joints (ID 1405, 1652, 1945)

- The claimed effects are “stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks, protection against”, “essential part of the connective tissues, skin and hair”, and “bioavailable silicon form, silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels”. The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the maintenance of normal joints. Maintenance of normal joints is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of silicon and maintenance of normal joints.

Maintenance of normal appearance and elasticity of the skin (ID 288, 333)

- The claimed effects are “normal skin, hair and nails”, and “maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis”. The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the maintenance of normal appearance and elasticity of the skin.
- The claim does not refer to a function of the body as required by Regulation (EC) No 1924/2006.

Contribution to normal formation of hair and nails (ID 334, 1652, 1719)

- The claimed effects are “helps support hair quality by helping to maintain healthy connective tissue in the dermis”, “essential part of the connective tissues, skin and hair”, and “helps support hair quality by helping to maintain healthy connective tissue in the dermis, healthy

women and men". The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the contribution to normal formation of hair and nails. Contribution to normal formation of hair and nails is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of silicon and contribution to the normal formation of hair and nails.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1074, EFSA-Q-2008-1075, EFSA-Q-2008-1076, EFSA-Q-2008-1077, EFSA-Q-2008-1120, EFSA-Q-2008-1121, EFSA-Q-2008-1122, EFSA-Q-2008-1132, EFSA-Q-2008-2142, EFSA-Q-2008-2388, EFSA-Q-2008-2454, EFSA-Q-2008-2455, EFSA-Q-2008-2678). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁸ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁹

Foods are commonly involved in many different functions¹⁰ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁸ OJ L12, 18/01/2007

⁹ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

¹⁰ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to silicon, including conditions of use from similar claims, as proposed in the Consolidated List.

| ID | Food or Food constituent | Health Relationship | Proposed wording |
|-----|--|---|--|
| 287 | Silicon | Silicon is required for normal bone and connective tissue formation | Silicon is required for normal bone and connective tissue formation. |
| | Conditions of use <ul style="list-style-type: none"> - Guidance level is 700mg/day or less from supplements (FSA). Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006 - 5-10 mg of OSA Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. - Food supplement with 196-588 mg (15-45 ml) of silicon in the daily dose - Food supplement with 100mg of silicon in the daily dose - Silicon acid gel - Amount of consumption: ab 20 mg/l Slizium - Daily intake of 6-10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 3-5 mg Si in the morning and 3-5 mg Si in the evening. Healthy females and males. | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 288 | Silicon and Silicon (as stabilized Oligomeric orthosilicic acid (OSA) | Normal skin, hair and nails. | <p>Silicon is required for healthy skin, hair and nails.</p> <p>Silicon is beneficial for collagen formation in the skin; Silicon reduces the appearance of wrinkles as it stimulates the formation of collagen and helps improve skin elasticity;</p> |
| | Conditions of use <ul style="list-style-type: none"> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006 - Food supplements with at least 100mg of silicon in the daily dose - Silicon acid gel with 196-588mg of silicon in the daily serving Product contains only silicon oxide and water. - Silicon acid gel food supplement with 196-588mg of silicon in the daily dose Product contains only silicon oxide and water. - 363 mg per day - Daily intake of 10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening. Healthy females and males. | | |

| | <ul style="list-style-type: none"> - Daily intake of 10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening | | |
|-----|---|---|--|
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 289 | Silicon (as stabilized Oligomeric orthosilicic acid (OSA)) | Cardiovascular health | <p>Silicon is beneficial for cardiovascular health;</p> <p>Silicon supports the health of the cardiovascular system; Silicon helps to maintain the health of blood vessels</p> |
| | Conditions of use <ul style="list-style-type: none"> - 5-10 mg of OSA <p>Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.</p> <ul style="list-style-type: none"> - Food supplement with at least 100mg of silicon in the daily dose | | |
| | Comments from Member States <p>No further clarification received</p> | | |
| | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 290 | Silicon (as stabilized oligomeric orthosilicic acid (OSA)) | Mental health | <p>Silicon helps protect the brain; Silicon reduces aluminium accumulation in the brain</p> |
| | Conditions of use <ul style="list-style-type: none"> - 5- 10 mg of OSA <ul style="list-style-type: none"> - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. | | |
| | No clarification provided by Member States | | |
| | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 333 | cholinestabilized orthosilicic acid (ch-OSA) (The mineral silicon (Si) is present in water as orthosilicic acid (OSA), ch-OSA is a stabilized and concentrated source of orthosilicic acid) | Maintenance and promotion of healthy connective tissue in skin by stimulating collagen synthesis in the dermis. | <p>helps reduce the appearance of wrinkles</p> <ul style="list-style-type: none"> - helps improve skin elasticity |
| | Conditions of use <ul style="list-style-type: none"> - Daily intake of 10 mg silicon (Si) in the form of cholinestabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening <p>Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.</p> <ul style="list-style-type: none"> - Daily intake of 10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening | | |
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| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 334 | cholinestabilized | Helps support | - helps improve hair thickness |

| | <p>orthosilicic acid (ch-OSA) (The mineral silicon (Si) is present in water as orthosilicic acid (OSA), ch-OSA is a stabilized and concentrated source of orthosilicic acid)</p> | <p>hairquality by helping to maintain healthy connective tissue in the dermis.</p> | <p>- helps maintain hair strength and hair elasticity</p> |
|---|--|---|--|
| <p>Conditions of use</p> <ul style="list-style-type: none"> - Daily intake of 10 mg silicon (Si) in the form of cholinestabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening. Healthy females and males. <p>Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.</p> <ul style="list-style-type: none"> - Daily intake of 10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening. - Daily intake of 5-10 mg of stabilized Oligomeric orthosilicic acid | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 335 | <p>cholinestabilized orthosilicic acid (ch-OSA) (The mineral silicon (Si) is present in water as orthosilicic acid (OSA), ch-OSA is a stabilized and concentrated source of orthosilicic acid)</p> | <p>Maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis.</p> | <p>helps support bone quality by stimulating bone collagen</p> <p>- helps maintain strong bones</p> |
| <p>Conditions of use</p> <ul style="list-style-type: none"> - Daily intake of 6-10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 3-5 mg Si in the morning and 3-5 mg Si in the evening. - Daily intake of 6-10 mg silicon (Si) in the form of cholinestabilized orthosilicic acid (ch-OSA); 3-5 mg Si in the morning and 3-5 mg Si in the evening. Healthy females and males. <p>Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.</p> <ul style="list-style-type: none"> - Daily intake of 5-10 mg of stabilized Oligomeric orthosilicic acid | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 345 | Silicon | <p>Gut health</p> <p><u>Clarification provided</u></p> <p>Forms a protecting coat on the mucous membrane of the stomach</p> <p>Neutralizes stomach acids thus calming irritated stomach</p> | <p>For stomach health.</p> <p>Sooths the stomach</p> <p>Protects the stomach's mucous membranes.</p> |
| <p>Conditions of use</p> <ul style="list-style-type: none"> - Food supplement with silicon starting from 100mg in the daily dose | | | |

| | <p>- Food supplement with colloid silicon (silicon oxide dispersed in water) content of 3g/100g, 450-1350mg/daily dose</p> <p>Comments from Member States</p> <p>Health relationship defined</p> | | |
|------|---|---|---|
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1405 | Mineralwasser/ Kieselsäure (Silizium) <u>Clarification provided</u> Mineral water/silicic acid (silicon) | Festigkeit des Bindegewebes/ Zellgewebes <u>Clarification provided</u> stability of the connective/cell tissue; strengthening the joint cartilage and the intervertebral disks; Protection against | [In german :] stärkt/festigt das Bindegewebe <u>Clarification provided</u> –strengthens/stabilizes the connective tissue |
| | <p>Conditions of use</p> <p>- Amount of consumption: ab 20 mg/l Slizium</p> | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1652 | Silica / Silicious earth | Essential part of the connective tissues, skin and hair | Plays an important part in the connective tissue/ helps maintain healthy hair, skin and nails/ helps strengthen skin, hair and nails/ helps maintain healthy skin, joints and bone and strong hair and nails/ traditionally used to contribute to the condition |
| | <p>Conditions of use</p> <p>- Typical intake: 20-500 mg silicon per day</p> <p>- No RDA dose defined yet. Typical intake: 20-50 mg silicon per day</p> <p>- 500 mg/day</p> | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1718 | choline-stabilized orthosilicic acid (ch-OSA) (The mineral silicon is present in water as orthosilicic acid; ch-OSA is a stabilized and concentrated source of orthosilicic acid) | Maintenance and promotion of healthy connective tissue in bone by stimulating bone collagen synthesis. Healthy women and men. | <p>- helps support bone quality by stimulating bone collagen</p> <p>- helps maintain strong bones</p> <p>- helps maintain bone mineral density</p> <p>- helps maintain healthy bones</p> |
| | <p>Conditions of use</p> <p>- Daily intake of 6-10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 3-5 mg Si in the morning and 3-5 mg Si in the evening</p> <p>- Daily intake of 10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening</p> | | |

| ID | Food or Food constituent | Health Relationship | Proposed wording |
|------|--|--|---|
| 1719 | choline-stabilized orthosilicic acid (ch-OSA) (The mineral silicon is present in water as orthosilicic acid; ch-OSA is a stabilized and concentrated source of orthosilicic acid) | Helps support hair quality by helping to maintain healthy connective tissue in the dermis. Healthy women and men. | helps improve hair thickness - helps maintain hair strength and hair elasticity - helps improve hair volume - helps maintain healthy hair |
| | Conditions of use - Daily intake of 10 mg silicon (Si) in the form of choline-stabilized orthosilicic acid (ch-OSA); 5 mg Si in the morning and 5 mg Si in the evening. | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1945 | Monométhylsilanetriol: other substance with nutritional or physiological effects | Bioavailable Silicon form. Silicon is an essential element for normal structure of connective tissues such as skin, hair, joints, bone and blood vessels | Contributes to maintenance of healthy skin, joints and bone. -Contributes to maintenance of strong hairs and nails. -Contributes to the structure of blood vessels. -Supports mobility and flexibility by contribution to the structure of articular cartilage |
| | Conditions of use - Typical intake: 20-500 mg silicon per day | | |

GLOSSARY AND ABBREVIATIONS

| | |
|--------|---|
| BAP | Bone specific alkaline phosphatase |
| BMD | Bone mineral density |
| ch-OSA | choline-stabilised orthosilicic acid |
| CTX-I | C-terminal telopeptide of type I collagen |
| DPD | Deoxypyridoline |
| DXA | Dual-energy x-ray absorptiometry |
| EPIDOS | Epidemiology of osteoporosis |
| OC | Osteocalcin |
| OSA | Orthosilicic acid |
| PINP | Procollagen type I N-terminal propeptide |